Complete Summary

GUIDELINE TITLE

Diagnosis and management of adults with chronic kidney disease.

BIBLIOGRAPHIC SOURCE(S)

Michigan Quality Improvement Consortium. Diagnosis and management of adults with chronic kidney disease. Southfield (MI): Michigan Quality Improvement Consortium; 2006 Nov. 1 p.

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- July 31, 2008, Erythropoiesis Stimulating Agents (ESAs): Amgen and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of modifications to certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of prescribing information for Erythropoiesis Stimulating Agents (ESAs). The changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should be initiated.
- November 8, 2007 and January 3, 2008 Update, Erythropoiesis Stimulating Agents (ESAs): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of revised boxed warnings and other safety-related product labeling changes for erythropoiesis-stimulating agents (ESAs) stating serious adverse events, such as tumor growth and shortened survival in patients with advanced cancer and chronic kidney failure.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Chronic kidney disease (CKD)

GUIDELINE CATEGORY

Diagnosis
Management
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Nephrology

INTENDED USERS

Advanced Practice Nurses Health Plans Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To achieve significant, measurable improvements in the diagnosis and aggressive management of chronic kidney disease (CKD) through the development and implementation of common evidence-based clinical practice quidelines
- To design concise guidelines that are focused on key management components of chronic kidney disease to improve outcomes

TARGET POPULATION

- Adults at increased risk for chronic kidney disease (CKD)
- Adults with chronic kidney disease

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Diagnosis

Assessment of markers of kidney damage (e.g., blood pressure measurement, estimated glomerular filtration rate [GFR], protein-to creatinine or albumin-to-creatinine ratio, urinalysis, fasting lipid profile, electrolytes, blood urea nitrogen (BUN)

Management/Treatment

- 1. Evaluation and management of comorbid conditions such as diabetes, hypertension, urinary tract obstruction, cardiovascular disease
- 2. Review of medications for dose adjustment, drug interactions, adverse effects, and therapeutic levels
- 3. Patient education on lifestyle changes such as dietary sodium restrictions, weight maintenance, weight loss, exercise, smoking cessation
- 4. Development of clinical action plan for each patient based on disease stage
- 5. Incorporation of self-management behaviors into treatment plan at all stages
- 6. Management according to kidney disease stage
 - Monitoring GFR
 - Smoking cessation and maintenance of blood pressure and lipid goals
 - Nephrology/renal dietician referral or consult
 - Aspirin therapy
 - Angiotensin-converting enzyme (ACE) inhibitor/angiotensin receptor blocker therapy
 - Suppression of parathyroid hormone levels with vitamin D
 - Phosphorus lowering treatment
 - Correction of iron deficiency
 - Epoetin therapy
 - Vaccine updates
 - Renal replacement therapy

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Michigan Quality Improvement Consortium (MQIC) project leader conducts a search of current literature in support of the guideline topic. Computer database searches are used to identify published studies and existing protocols and/or clinical practice guidelines on the selected topic. A database such as MEDLINE and two to three other databases are used.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for the Most Significant Recommendations

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational studies
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Using the health plan guideline summaries and information obtained from the literature search, the Michigan Quality Improvement Consortium (MQIC) director and/or project leader prepare a draft guideline for review by the MQIC Medical Directors.

The draft guideline and health plan guideline summaries are distributed to the MQIC Medical Directors for review and discussion at their next committee meeting.

The review/revision cycle may be conducted over several meetings before consensus is reached. Each version of the draft guideline is distributed to the MQIC Medical Directors, Measurement, and Implementation Committee members for review and comments. All feedback received is distributed to the entire membership.

Once the MQIC Medical Directors achieve consensus on the draft guideline, it is considered approved for external distribution to practitioners with review and comments requested.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Once the Michigan Quality Improvement Consortium (MQIC) Medical Directors achieve consensus on the draft guideline, it is considered approved for external distribution to practitioners with review and comments requested.

The MQIC director also forwards the approved guideline draft to presidents of the appropriate state medical specialty societies for their input. All feedback received from external reviews is presented for discussion at the next MQIC Medical Directors Committee meeting. In addition, physicians are invited to attend the committee meeting to present their comments.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The level of evidence grades (A-D) are provided for the most significant recommendations and are defined at the end of the "Major Recommendations" field.

Screening and Diagnosis

All Adults at Increased Risk for Chronic Kidney Disease (CKD)

For patients at increased risk for CKD (e.g., diabetes, hypertension, family history of kidney failure, kidney stones, etc.) assess for markers of kidney damage:

- Measure blood pressure [A]
- Obtain estimated glomerular filtration rate (GFR)¹ (serum creatinine levels should not be used as sole means to assess renal function)
- Protein-to-creatinine ratio **or** lbumin-to-creatinine ratio (first morning or random spot urine specimen)
- Urinalysis, fasting lipid profile, electrolytes, blood urea nitrogen (BUN)

Frequency

Semi-annual blood pressure monitoring; more frequent monitoring if indicated

Monitor GFR every 1–2 years

¹If not calculated by lab, refer to the National Kidney Foundation website for GFR calculator (http://www.kidney.org/professionals/tools/)

Risk Factor Management and Patient Education

All Adults at Increased Risk for CKD

- Evaluation and management of comorbid conditions (e.g. diabetes, hypertension, urinary tract obstruction, cardiovascular disease)²
- Review medications for dose adjustment, drug interactions, adverse effects, therapeutic levels
- Educate on therapeutic lifestyle changes: dietary sodium intake < 2.4 grams/day (g/d) recommended for patients with CKD and hypertension [A], weight maintenance if body mass index (BMI) <25, weight loss if BMI ≥ 25, exercise and physical activity, moderation of alcohol intake, smoking cessation

Frequency. At each routine health exam

²Reference MQIC guidelines on diabetes, hypertension, hyperlipidemia and obesity (http://www.mqic.org).

Adults with CKD

All of the above plus:

- Develop clinical action plan for each patient, based on disease stage as defined by the National Kidney Foundation, Kidney Disease Outcomes Quality Initiative (K/DOQI) [B]
- Incorporate self-management behaviors into treatment plan at all stages of CKD [B]

Frequency. At each routine health exam

Core Principles of Treatment

Adults with CKD

- Stage 1 (GFR >90): Monitor GFR annually, smoking cessation, consider aspirin (ASA), consider angiotensin converting enzyme (ACE) and/or angiotensin receptor blocker (ARB) therapy, blood pressure (BP) goal <130/80, low density lipoprotein-cholesterol (LDL-C) goal <100
- Stage 2 (GFR 60-89): Nephrology referral if GFR decline > 4ml/min/yr, maintain BP and lipid goals as above
- **Stage 3 (GFR 30–59)**: Consult Nephrologist and Renal Dietician; Suppress parathyroid hormone (PTH) with vitamin D to level appropriate for CKD stage; Phosphorus lowering treatment if > 4.6 mg/dl; Correct iron deficiency before start of epoetin therapy; Epoetin if hemoglobin (Hgb) (hematocrit [Hct]) <11 (33%); renal-specific vitamins; Update vaccines: hepatitis B virus (HBV),

- influenza, diphtheria/tetanus acellular pertussis vaccine (Tdap) and Pneumovax
- **Stage 4 (GFR 15–29)**: Nephrology and vascular access surgery referrals, Epoetin if Hct <33%, Optimize Ca x P product to < 55 with specific agents, update vaccines as indicated, CKD education classes
- Stage 5 (GFR <15): Renal replacement therapy

Frequency. As indicated

Definitions:

Levels of Evidence for the Most Significant Recommendation

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational studies
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is provided for the most significant recommendations (see "Major Recommendations" field).

This guideline is based on several sources, including: the 2002 National Kidney Foundation/Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification (www.kidney.org).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Through a collaborative approach to developing and implementing common clinical practice guidelines and performance measures for diagnosis and aggressive management of chronic kidney disease (CKD), Michigan health plans will achieve consistent delivery of evidence-based services and better health outcomes. This approach also will augment the practice environment for physicians by reducing the administrative burdens imposed by compliance with diverse health plan guidelines and associated requirements.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline lists core management steps. Individual patient considerations and advances in medical science may supersede or modify these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

When consensus is reached on a final version of the guideline, a statewide mailing of the approved guideline is completed. The guideline is distributed to physicians in the following medical specialties:

- Family Practice
- General Practice
- Internal Medicine
- Other Specialists for which the guideline is applicable (e.g., endocrinologists, allergists, pediatricians, cardiologists)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

This guideline is based on the 2002 National Kidney Foundation/Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification (www.kidney.org).

DATE RELEASED

GUIDELINE DEVELOPER(S)

Michigan Quality Improvement Consortium - Professional Association

SOURCE(S) OF FUNDING

Michigan Quality Improvement Consortium

GUIDELINE COMMITTEE

Michigan Quality Improvement Consortium Medical Director's Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Physician representatives from participating Michigan Quality Improvement Consortium health plans, Michigan State Medical Society, Michigan Osteopathic Association, Michigan Association of Health Plans, Michigan Department of Community Health and Michigan Peer Review Organization

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Michigan</u> <u>Quality Improvement Consortium Web site</u>.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on July 13, 2007. The information was verified by the guideline developer on July 16, 2007. This summary was updated by ECRI Institute on March 21, 2008 following the FDA advisory on Erythropoiesis Stimulating Agents. This summary was updated by ECRI Institute on August 15, 2008 following the U.S. Food and Drug Administration advisory on Erythropoiesis Stimulating Agents (ESAs).

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